PATENT
Attorney Docket No. A-68983-2
Dorsey File No. 469443-00065

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	Examiner: JALLA, Sanjoo
HORWITZ	Art Unit: 1644
Serial No.: 10/772,768	
Filing Date: February 4, 2004	
For: *Method to Prevent Graft Rejection Using TGF-Beta to Induce T Suppressor Cells*	

DECLARATION PURSUANT TO 37 C.F.R. § 1.132

Mail Stop Amendment
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

I, **David A. Horwitz**, having a residence at 566 Latimer Rd, Santa Monica, CA and being a U.S. citizen, do hereby declare as follows:

1. I am the inventor on the above-identified patent application and am familiar with its contents. I have also reviewed the pending claims in this application.

2. I have read the Examiner's comments in the Office Action mailed on February 28, 2006. As I understand it, the Examiner has rejected claims 1-6 primarily because the suppressor T cells recited in the pending claims are allegedly anticipated under 35 U.S.C. §102(b) by

McIntosh et al. U.S. Patent No. 6,685,936 (hereinafter "McIntosh") and in Hall et al. J. Exp. Med. 1990; 171:141-157 (hereinafter "Hall").

3. The Examiner cites McIntosh as teaching suppressor T cells capable of treating (i.e. decreasing) transplant rejection and that such cells may be CD8+. Hall is cited by the Examiner for teaching CD4+ suppressor T cells capable of inhibiting restoration of transplant rejection (i.e. decreasing transplant rejection).

4. The presently claimed suppressor T cells differ from the suppressor T cells disclosed in either Hall or McIntosh. That is, the claimed cells do not require CD8+ cells to have suppressive activity.

5. The presently claimed suppressor T cells have suppressive activity independent of CD8+ cells. Examples 1 and 3 of the application describe CD4+ suppressor T cells prepared by the methods of the present invention, which have suppressive activity.

6. In contrast, the suppressive ability of the suppressor T cells disclosed by the references is CD8+ cell-dependent.

7. Hall discloses treating cyclosporine-treated host animals having donor grafts with an anti-CD8+ antibody to deplete CD8+ cells and subsequent administration of CD4+ suppressor T cells. It was observed that the CD8+ cell-depleted animals rejected their grafts, while animals having CD8+ cells did not reject their grafts (Table V and page 148 1st paragraph).

8. McIntosh discloses the preparation of suppressor T cells that are CD8 depleted (Col. 7, lines 38-41). When such CD8+-depleted cells are pre-cultured with human mesenchymal stem cells, a partial and delayed suppression of a mixed lymphocyte reaction is observed (Fig. 2-3). The reference further discloses that this result suggests that the suppressive activity of its suppressor T cells requires CD8+ cells (Col. 8, lines 22-24).

9. Both Hall and McIntosh disclose experimental data showing that their suppressor T cell activity is dependent on CD8+ cells. The claimed suppressor T cells have suppressive activity independent of CD8.

10. I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that the making of willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful statements may jeopardized the validity of the application or any patent issuing thereon.

Date: Aug 19, 2006

David A. Horwitz

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